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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
1001.2560102

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on JUNE 25, 2010

Signature

Typed or printed name THU H. LE-TO

Application Number	Filed
10/786,322	February 25, 2004

First Named Inventor: DANIEL M LAFONTAINE

Art Unit	Examiner
3739	ROY DEAN GIBSON

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 41,376
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

J. SCOT WICKHEM
Typed or printed name

612.677.9050
Telephone number

June 25, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of _____ forms are submitted.

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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	DANIEL M LAFONTAINE	Confirmation No.:	2641
Serial No.:	10/786,322	Examiner:	Roy Dean Gibson
Filing Date:	February 25, 2004	Group Art Unit:	3739
Docket No.:	1001.2560102	Customer No.:	28075
Title:	CRYO-TEMPERATURE MONITORING		

PRE-APPEAL CONFERENCE BRIEF

Mail Stop AF
Commissioner for Patents
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CERTIFICATE FOR ELECTRONIC TRANSMISSION

The undersigned hereby certify that this paper(s), as described herein, is being electronically transmitted to the U.S. Patent and Trademark Office on the date shown below

Thu H. Le-To — JUNE 25, 2010 (Date)

Applicants have carefully reviewed the Final Office Action mailed December 30, 2009. Applicants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Applicants respectfully submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

The drawings were objected to as failing to comply with 37 C.F.R. 1.84(p)(5) because "they do not include reference sign(s) for the first and second balloon nor are there reference signs or numbers for these elements in the Specification." Applicant respectfully traverses the objection. The Examiner cites to 37 C.F.R. 1.84(p)(5) for authority for the objection. However, 37 C.F.R. 1.84(p)(5) states that:

> Reference characters not mentioned in the description shall not appear in the drawings. Reference characters mentioned in the description must appear in the drawings.

Nothing in the cited authority appears to provide any basis for objecting to both the drawings and

the specification as not including reference characters. Nowhere does the Final Office Action appear to identify any reference characters not mentioned in the description that appear in the drawings or any reference characters that are mentioned in the description that do not appear in the drawings.

Furthermore, it appears that the Final Office Action is attempting to combine to form paragraphs found in MPEP 608.02(e), specifically, the two following form paragraphs:

> ¶ *6.22.06 Drawings Objected to, Reference Numbers Not in Drawings*
> The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **[1]**. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
>
> ¶ *6.22.07 Drawings Objected to, Reference Numbers Not in Specification*
> The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **[1]**. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d) If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant respectfully submits that this combination is clearly improper. Further, nothing in 37 CFR 1.84(p)(5) appears to provide any basis for this objection. As such, Applicant submits that the drawings and specification are in compliance with 37 C.F.R. 1.84(p)(5). Withdrawal of the objection is respectfully requested. If this objection is to be maintained, Applicant respectfully requests proper authority be provided to support the objection.

Claims 43, 44, 46, and 49 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Wittenberger et al. (U.S. Patent No. 6,575,933) in view of Hammack et al. (U.S. Patent No. 6,679.906). Applicant respectfully traverses the rejection. Turning to claim 43, which recites:

> 43. (Previously Presented) A device for minimally invasive medical treatment in a
> body of a patient, comprising:
> a tubular member having a proximal end and a distal end;
> a cryo therapy apparatus connected to the distal end of the tubular member, wherein the cryo therapy apparatus comprises a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails; and
> an optical sensor to monitor temperatures created by use of the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus;
> wherein the cryo therapy apparatus is sized and arranged for vascular introduction.

Neither Wittenberger et al. or Hammack et al., taken either alone or in combination, appear to disclose many elements of claim 43, including for example, "a cryo therapy apparatus connected to the distal end of the tubular member, wherein the cryo therapy apparatus comprises a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails".

In the Final Office Action, the Examiner cites to element 610 of Wittenberger et al. as providing a first balloon and element 630 as providing a second balloon. With regards to elements 610 and 630, Wittenberger et al. recites:

> Specifically, FIG. 13 shows a catheter whose proximal segment 600 preferably includes within it an air supply line 605 and a fluid supply line 620. The air

> supply line 605 terminates in an inner balloon 610, shown in an expanded condition. It should be noted that air inflation of the inner balloon 610 is merely one of a number of possible expansion methods. The inner balloon 610 has surrounding it a plurality of members 630, spaced radially apart around a longitudinal axis of the inner balloon 610. In this expanded condition, the members 630 contact an inner side 617 of an outer balloon 615. Cryogenic fluid may preferably be introduced into the space 618 created in this arrangement between the inner balloon 610 and the outer balloon 615 through fluid supply line 620.

(Emphasis added, column 8, lines 25-38.) As can be seen, Wittenberger et al. appears to disclose an inner balloon 610 surrounded at least in part by an outer balloon 615, the inner balloon 610 appears to be inflated by air or other suitable expansion method and the cryogenic fluid appears to be introduced into the space 618 created between the inner balloon 610 and the outer balloon 615. To further illustrate balloons 610 and 630, Figure 13 has been reproduced below:

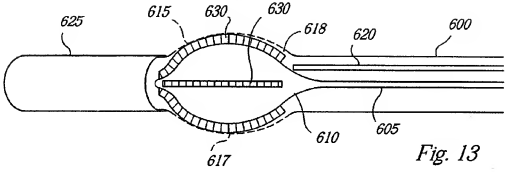

Fig. 13

As can be seen, nothing in the reproduced passage or Figure of Wittenberger et al. appears to disclose "a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails", as recited in claim 43. Further, nowhere does the Final Office Action appear to cite any portion of Wittenberger et al. as disclosing this feature. Further, nowhere does the Final Office Action appear to cite any portion of Hammack et al. as curing the noted shortcomings of Wittenberger et al. For at least these reasons, claim 43 is believed to be patentable over Wittenberger et al. in view of Hammack et al. For similar and other reasons, claims 44, 46, and 49, which depend from claim 43 and include additional distinguishing features, are also believed to be patentable over Wittenberger et al. in view of Hammack et al.

Withdrawal of the rejection is respectfully requested.

Claim 52 stands finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Wittenberger et al. in view of LePivert (U.S. Patent No. 6,551,309). Applicant respectfully traverses the rejection. Nothing in the cited portions of Wittenberger et al. or Hammack et al., taken either alone or in combination, appear to disclose many elements of claim 52, including for example, "a cryo therapy apparatus connected to the distal end of the tubular member and comprising a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails and prevent loss of the coolant to the body of the patient". For similar reasons discussed above with reference to claim 43, as well as other reasons, claim 52 is believed to be patentable over Wittenberger et al. in view of LePivert. Reconsideration and withdrawal of the rejection are respectfully requested.

Reconsideration and withdrawal of the rejection are respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

DANIEL M LAFONTAINE

By his Attorney,

Date: June 25, 2010

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